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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,698	06/02/2005	Magnus Von Knebel-Doeberitz	03528.0145.00US00	9319
27194 7590 01/14/2010 HOWREY LLP-CA C/O IP DOCKETING DEPARTMENT 2941 FAIRVIEW PARK DRIVE, SUITE 200 FALLS CHURCH, VA 22042-2924				
EXAMINER AEDER, SEANE				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/511,698

Applicant(s)

VON KNEBEL-DOEBERITZ ET AL.

Examiner

SEAN E. AEDER

Art Unit

1642

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-79 is/are pending in the application.
- 4a) Of the above claim(s) 44, 48-51, 54-57 and 60-79 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-47, 52, 53, 58, and 59 is/are rejected.
- 7) ☒ Claim(s) 45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

The response filed on 12/3/09 to the restriction requirement of 6/4/09 has been received. Applicant has elected Group II for examination. Because Applicant did not distinctly and specifically point out any errors in the restriction requirement, the election has been treated as an election without traverse (MPEP 818.03(a)).

Claims 44-79 are pending.

Claims 44, 48-51, 54-57, 60-79 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claims 45-47, 52, 53, 58, and 59 are currently under consideration.

Claim Objections

Claim 45 is objected to for making reference to an unelected invention.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 45-47 are rejected under 35 U.S.C. 101 because claims 45-47, as written, does not sufficiently distinguish over peptides as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the

naturally occurring products are considered non-statutory subject matter. *See Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of "Isolated" or "Purified". See MPEP 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 45-47, 52, 53, 58, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Mayer et al (JBC, 1992, 267(29): 20589-20593).

Claim 45 encompasses a fragment peptide comprising a fragment of SEQ ID NO:20, wherein said fragment peptide comprises at least 3 amino acids of a mutated part of SEQ ID NO:20 and has a length of at least 15 amino acids. It is noted that claim 45 does not limit said fragment polypeptide as being a fragment of any particular polypeptide. Claim 46 is drawn to the fragment peptide of claim 45 wherein said fragment peptide comprises an immunogenic portion with a length of about 10-20 amino acids. Claim 47 is drawn to the fragment peptide according to claim 45, wherein the three amino acids are TIL. Claim 52 is drawn to a composition comprising the fragment peptide according to claim 45 and a physiologically acceptable carrier. Claim 53 is drawn to a composition comprising the fragment peptide according to claim 47 and a

physiologically acceptable carrier. Claim 58 is drawn to a kit comprising the fragment peptide according to claim 45 and additional reagents and buffers for carrying out detection reactions. Claim 59 is drawn to a kit comprising the fragment peptide according to claim 47 and additional reagents and buffers for carrying out detection reactions.

Mayer et al teaches "Ras-Cys-Thr-Ile-Leu", which is a peptide comprising a fragment of instant SEQ ID NO:20, wherein said fragment peptide comprises amino acids TIL of instant SEQ ID NO:20, has a length of at least 15 amino acids, and wherein said fragment peptide comprises an immunogenic portion with a length of about 10-20 amino acids (see page 20590, in particular). Mayer et al further teaches a composition which is a gel that comprises Ras-Cys-Thr-Ile-Leu and the physiologically acceptable carrier water (see Figure 3, in particular). Mayer et al further teaches use of a kit comprising Ras-Cys-Thr-Ile-Leu and additional reagents and buffers for carrying out detection reactions (see Figure 3, in particular).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 47, 53, and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a **NEW MATTER** rejection.

Claims 47, 53, and 59 are drawn to fragment peptides which comprise at least the three amino acids "TIL" of SEQ ID NO:20. Descriptions of fragment peptides which comprise at least the three amino acids "TIL" of SEQ ID NO:20 are not found in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention.

In the Reply of 3/23/09, Applicant indicates fragment peptides which comprise at least the three amino acids "TIL" of SEQ ID NO:20 are supported by FIG. 2-2, TAF1b (-1).

The arguments found in the Reply of 3/23/09 have been carefully considered, but are not deemed persuasive. In regards to the argument that fragment peptides which comprise at least the three amino acids "TIL" of SEQ ID NO:20 are supported by FIG. 2-2, TAF1b (-1), FIG. 2-2, TAF1b (-1) does not provide support for the genus of fragment peptides which comprise at least the three amino acids "TIL" of SEQ ID NO:20. Rather, FIG. 2-2, TAF1b (-1) provides support for polypeptides comprising instant SEQ ID NO:20.

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN E. AEDER whose telephone number is (571)272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean E Aeder/
Primary Examiner, Art Unit 1642